

K060948
510(k) Summary for the
Rhytec, Inc. Portrait PSR3

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This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:

Rhytec, Inc.
1000 Winter Street
Waltham, MA 02451

Contact Person:

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Telephone: 978-207-1245
Fax: 978-207-1246

Summary Preparation Date:

March 31, 2006

2. Names

Device Name:

Portrait PSR3

Classification Name:

Electrosurgical cutting and coagulation
device
Product Code: GEI

3. Predicate Devices

The Portrait PSR3 is substantially equivalent to the Gyrus Medical, Inc. Plasma Skin Resurfacing (PSR) System (K041999) and the Thermage ThermoCool System (K053365, K052778, K021402, and K013639).

4. Device Description

The Rhytec, Inc. Portrait PSR3 is an electro-surgical device for use in dermatological applications. UHF energy from the generator converts Nitrogen gas into plasma within the handpiece. The plasma emerges from the nozzle at the distal end of the handpiece and is directed onto the skin to be treated. Rapid heating of the skin occurs as the excited gas gives up energy to the skin. Through the combination within the handpiece of precisely controlled energy and Nitrogen gas, individual plasma pulses are produced that will give predictable tissue effects.

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5. Indications for Use

The Portrait PSR3 is indicated for treatment of the following dermatological conditions:

- Treatment of wrinkles and rhytides
- Superficial skin lesions
- Actinic Keratosis
- Viral Papillomata
- Seborrhoeic Keratosis

6. Performance Data

A clinical study was conducted which included 10 subjects treated in 30 anatomical sites which showed significant improvement in each of the three anatomic regions observed. Reduction in skin dyspigmentation and wrinkle severity was observed in neck and chest skin and in the skin of the dorsum of the hands.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2006

Rhytec, Inc
% Ms. Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
1000 Winter Street
Waltham, Massachusetts 02451

Re: K060948

Trade/Device Name: Rhytec, Inc. Portrait PSR3
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting coagulation device and accessories
Regulation Class: Class II
Product Code: GEI
Dated: August 7, 2006
Received: August 9, 2006

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Maureen O'Connell

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkers", is written over a horizontal line.

Mark N. Melkers
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060948

Device Name: Rhytec, Inc. Portrait PSR3

Indications for Use:

The Portrait PSR3 is indicated for treatment of the following dermatological conditions:

- Treatment of wrinkles and rhytides
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- Viral Papillomata
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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General Restorative,
and Neurological Devices

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